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07/649,342	02/01/91	DE 11	FIRST NAMED APPLICANT	ATTY. DOCKET NO. <u>mk</u> 03495-0059-0
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FINNEGAN, HENDERSON, FARABOW,
GARRETT AND DUNNER
1300 I STREET, N.W.
WASHINGTON DC 20005-3315

HM22/0304

EXAMINER

ULM, J

ART UNIT PAPER NUMBER

1646

38

DATE MAILED: 03/04/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Remand from BPAI Ex-recommendation

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-14, 24-34, 39-59 is/are pending in the application.
Of the above, claim(s) 58 is/are withdrawn from consideration.
- ☒ Claim(s) 32, 54 is/are allowed.
- ☒ Claim(s) 1-14, 24-31, 33, 34, 39-53, 57, 59 is/are rejected.
- ☒ Claim(s) 55, 56 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

ENCLOSING PAGES--

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- 1) Claims 1 to 14, 24 to 34, and 39 to 59 are pending in the instant application.

Claim 58 stands withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as drawn to a non-elected invention.

- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

- 4) The rejection of claims 1 to 14, 24 to 34, 39 to 57 and 59 under 35 U.S.C. § 103 as being unpatentable over the Petrovich et al. publication in view of the Hauptmann et al. and Krust et al. publications for reasons of record has been reconsidered and withdrawn in light of the issuance of Patent Numbers 5,317,090, 5, 376,530 and 5, 468,617, with which the instant rejection would have been in conflict. Because this rejection was the only rejection under appeal the appeal is dismissed and PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below. To avoid abandonment of the application, appellant must file a reply under 37 CFR 1.111 (See 37 CFR 1.193(b)(2)).

- 5) Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not conceivably be infringed without infringing any of the claims from which it depends.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6) Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use a recombinant nucleic acid encoding a retinoic acid receptor having other than the amino acid sequence that is presented in Figure 2 of the instant application. Claim 53 is a single means claim in that it encompasses any recombinant DNA molecule encoding any protein having the ligand and DNA binding properties of that single human protein described in the instant application. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt, 708 F.2d 712, 714 - 715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only

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those known to the inventor. See M.P.E.P. 2164.08(a). Further, the instant specification does not describe a recombinant DNA encoding a retinoic acid receptor having other than that single disclosed amino acid sequence.

7) Claims 10 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the instant specification does not provide the guidance needed to produce “a DNA probe” which consists essentially of a DNA sequence. A DNA sequence is nothing more than a property of a DNA molecule and not something that a molecule can “consist” of.

8) Claims 11 to 14 and 42 to 45 are rejected under 35 U.S.C. 112, first paragraph, because the instant specification does not provide the guidance needed to produce a hybrid duplex molecule “consisting essentially of” a DNA sequence and a nucleotide sequence. A “DNA sequence” and a “nucleotide sequence” are properties of a nucleic acid molecule and not material entities in and of themselves. Therefore, a molecule can not consist of a sequence. A nucleic acid molecule can either “comprise” a specific nucleotide sequence or it can “have” that sequence, but it can not “consist” of that sequence.

9) Claims 24 to 30, 34 and 46 to 52 are rejected under 35 U.S.C. 112, first paragraph, because the instant specification does not provide the guidance needed to practice the claimed process. First, the process as claimed requires the hybridization of a nucleotide “sequence” to a second nucleotide “sequence”. Because a nucleotide “sequence” is a property of a nucleic acid molecule it is not capable of hybridizing to anything. Second, the process as claimed requires the specific outcome of “selecting a nucleotide sequence coding for *hap*”

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protein...” whereas the only step recited in the claims is “determining which of said nucleotide sequences hybridizes to “ a specific DNA. No hybridization conditions are specified in the claims. Because nucleic acid molecules have an inherent affinity for one another irrespective of similarities or differences in their particular nucleotide sequences, any nucleic acid molecule will “hybridize” to any other nucleic acid molecule under the appropriate conditions. The instant claims are incomplete because they do not recite those precise hybridization conditions which allow a DNA molecule having the nucleotide sequence presented in Figure 2 of the instant application to hybridize to a nucleic acid encoding a retinoic acid receptor protein of the instant invention to the exclusion of all other nucleic acids, as would be required to practice the method as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10) Claim 1 recites the limitation "said DNA" in line 23. There is insufficient antecedent basis for this limitation in the claim. Claims 2, 3, 10 to 14, 24 to 31, 33, 34, 40 and 43 to 45 are vague and indefinite in so far as they depend from claim 1 for that limitation.

11) Claims 1 to 14, 24 to 31, 33, 34, 46 to 52 and 57 are vague and indefinite in the recitation of the term “*hap* gene” and/or “*hap* protein”. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of either a “*hap* gene” or a “*hap* protein” it is not possible for an artisan to determine if a compound which otherwise meets all of the material limitations of a claim would be included or excluded by the presence of this additional limitation.

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12) Claim 34 is indefinite and confusing because there is no basis for "[b]acterial culture as claim in claim 27".

13) Claim 53 is confusing in the recitation of the phrase "DNA sequence of coding for".

14) Claims 4 to 9, 53 and 57 are vague and indefinite in the recitation of the term "retinoic acid receptor- β polypeptide" ("RAR- β "). Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an "RAR- β " it is not possible for an artisan to determine if a compound which otherwise meets all of the material limitations of a claim would be included or excluded by the presence of this additional limitation.

15) Claim 57 is vague and indefinite because the numerical coordinates of the amino acid residues recited therein require a single point of reference and there is no single protein recognized in the art as "the mature retinoic acid receptor- β polypeptide".

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16) Claims 1 to 3, 39, 40 and 59 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claim are drawn to a "DNA sequence" which is nothing more than a property of a DNA molecule and not a material entity in and of itself.

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17) Claims 24 to 30, 34 and 46 to 52 are rejected under 35 U.S.C. 101 because the claimed invention is inoperative and therefore lacks utility. As stated above, these claims require the specific outcome of "selecting a nucleotide sequence coding for *hap* protein..." without reciting those minimal elements that are required to achieve this outcome.

18) Claims 32 and 54 are allowable as written.

19) Claims 55 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee can be reached at (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JOHN ULM
PRIMARY EXAMINER
GROUP 1800